

REMARKS

This amendment responds to the Office Action mailed on January 7, 2009. Accordingly, applicant submits that this response is being timely filed within two (2) months of the mailing of the Final Office Action, and applicant respectfully requests a response from the USPTO within the original shortened statutory period for response.

Claims 1-8, 12-13, 18-21, 32-34 and 39-40 are pending in the present application, and in the pages that follow below, applicant will set forth in detail that each of the pending claims are allowable over the cited prior art of record based on the following reasons:

- the newly cited *Ferek-Petric* reference is not prior art to the present application pursuant to 35 U.S.C. § 103(c)(1);
- the combination of the cited prior art references fails to teach or suggest continuous and real-time remote monitoring of continuously sensed physiologic information from a patient's medical device;
- the combination of the cited prior art references fails to teach or suggest determining a revenue based upon a user's access to the sensed physiologic information from a patient's medical device retrieved from a networked computing system; and
- the combination of the cited prior art references fails to teach or suggest an implantable medical device that wirelessly transmits sensed biologic data to a patient accessible electronic interface; and

Claim Rejections under 35 U.S.C. § 103

Claims 1-8, 12-13, 18-21, and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Brown* (US 5,997,476) and *Ferek-Petric* (US Pub. No. 2001/0044586) collectively in view of *Lynam* (US 6,934,372). Applicant respectfully traverses these rejections, and reconsideration is requested based on the following remarks.

Initially, applicant notes that *Ferek-Petric* is not prior art to the present application under 35 U.S.C. § 103(a), since *Ferek-Petric* only qualifies as prior art to the present application under 35 U.S.C. § 102(e) and both the present application and *Ferek-Petric* have been commonly owned by the same assignee, Medtronic, Inc. *Ferek-Petric* and the present application were co-pending, with the present application being filed on August 29, 2001 and *Ferek-Petric* being published on November 22, 2001. Thus, *Ferek-Petric* only qualifies as prior art to the present application under 35 U.S.C. § 102(e). Both the present application and *Ferek-Petric* have been subject to assignment by their respective inventors to Medtronic, Inc. and both the present application and *Ferek-Petric* were assigned to Medtronic, Inc. The assignment of the present application to Medtronic, Inc. is recorded at Reel 012636, Frame 0950 and the assignment of *Ferek-Petric* to Medtronic, Inc. is recorded at Reel 011752, Frame 0911. According to 35 U.S.C. § 103(c)(1), subject matter which qualifies as prior art only under 35 U.S.C. § 102(e) shall not preclude patentability under 35 U.S.C. § 103 where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. In this case, both the present application and *Ferek-Petric* were subject to assignment to Medtronic, Inc. at the time of invention and both are in fact owned by Medtronic, Inc. Thus, according to 35 U.S.C. § 103(c)(1), *Ferek-Petric* does not qualify as prior art to the present application under 35 U.S.C. § 103(a), and applicant respectfully requests that all rejections relying on the teachings of *Ferek-Petric* be withdrawn.

The Cited Prior Art Fails to Teach or Suggest Real-time Remote Monitoring of Continuously Sensed Physiologic Information From a Patient's Medical Device

Independent claims 1, 8 and 18 recite internet-based methods that receive at the database network site first data inputs uniquely representative of sensed physiologic information from a patient's medical device in a substantially continuous and real-time manner. Independent claim 33 recites a computer implemented internet-based method for an improved connect and monitoring service to rapidly connect remote persons having implantable medical devices to a database network for medical device data exchange and analysis enabling the user to access the database via the web-site to use the service for real time monitoring of high relevance physiologic data mined from all monitored data of the user.

Brown is cited in the Office Action as teaching "receiving in a substantially continuous and real-time manner at the database network site first data inputs uniquely representative of sensed physiologic information from a medical device configuration of a patient." However, Applicant notes that *Brown* fails to teach providing physiologic information from a patient's medical device in a substantially continuous and real-time manner to allow for real-time monitoring of such monitored physiologic data. The cited portion of *Brown* (col. 4, line 64 - col. 5, line 13) merely recites that measurements of a physiologic condition are measured, recorded and transmitted to a remote programmable apparatus. However, *Brown* does not teach real-time delivery of sensed physiologic information nor provide for real-time monitoring of sensed physiologic information. To the contrary, *Brown* teaches away from real-time monitoring and teaches that the advantages of its monitoring system are that it communications information from its monitoring system when it is convenient for a patient or when communication rates are the lowest. In particular, *Brown* teaches in column 11, lines 24-30:

One advantage of the monitoring system of the present invention is that it allows each patient to select a convenient time to respond to the queries, so that the monitoring system is not intrusive to the patient's schedule. A second advantage of the monitoring system is that it incurs very low communications charges because each remote apparatus connects to server 18 at times when communication rates are lowest.

According to § 2143.01 of the MPEP, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Thus, real-time reporting and monitoring of data from the monitoring system of *Brown* would appear contrary to its intended advantages and purpose of reducing costs by only communicating information at times when rates are their lowest and also at a time that is not intrusive to a patient's schedule. Thus, not only does *Brown* fail to teach or suggest an internet-based method for substantially continuous and real-time monitoring of patient data from a remote site, it also would not be obvious to modify *Brown's* teachings to achieve this feature because it would appear unsatisfactory for its intended purpose. For the foregoing reasons, applicant respectfully submits that independent claims 1, 8, and 18 and their respective dependent claims are not obvious in view of the combination of *Brown*, *Ferek-Petric* and *Lynam* or other cited prior art and applicant kindly requests reconsideration of these claims.

Applicant notes that claim 33 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Brown* (US 5,997,476) in view of *Bahl* (US 6,834,341), where claim 33 also recites a computer implemented internet-based method for an improved connect and monitoring service to rapidly connect remote persons having implantable medical devices to a database network for medical device data exchange and analysis enabling the user to access the database via the web-site to use the service for real time monitoring of high relevance physiologic data mined from all monitored data of the user. As discussed above, *Brown* fails to teach or suggest the real time monitoring of high relevance physiologic data through a database accessed through a website, and it is respectfully submitted that independent claim 33 and its respective dependent claims are also allowable over the combination of *Brown* and *Bahl* for the same reasons discussed above in connection with distinguishing independent claims 1, 8, and 18 from *Brown*.

The Combination of Cited Prior Art Fails to Teach or Suggest Determining a Revenue Based Upon a User's Access to a Networked Computing System to Retrieve Stored Physiologic Information That Has Been Sensed By a Patient's Medical Device

Independent claims 1 and 8 further recite internet-based methods that include determining a revenue based on a user's access to sensed physiologic information from a patient medical device (i.e., first data inputs) stored on the database network site or based on the user's access to a patient medical services delivery application program stored on the database network site.

It is admitted in the Office Action that *Brown* fails to teach or suggest determining a revenue based on a user's access to the networked computing system, where the Office Action cites *Lynam* to cure the deficiency of the *Brown* reference. Applicant respectfully traverses this characterization of *Lynam* and notes that the cited portion of *Lynam* is merely directed to a method of providing Internet access in which a user is charged for the time (e.g., number of minutes) the user is connected to the Internet through the Internet service provider (col. 2, lines 39-50). However, *Lynam* is not directed in any manner to a patient monitoring system, and *Lynam* fails to teach or suggest charging revenue or a fee for accessing a patient's medical records or for accessing medical data about a patient that has been sensed by an implantable medical device. At best, one skilled in the art would be motivated to modify the teachings of *Brown* in view of the Internet access charging mechanism of *Lynam* to charge a user of a workstation 20 for how long they are connected to the communication network 24 of *Brown*. Further, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

There is simply no teaching or suggestion by the combination of *Brown* and *Lynam* for determining a revenue based on a user's access to sensed physiologic information from a patient's medical device (i.e., first data inputs) stored on the database network site or based on access to information stored in a database concerning the patient structured to assist the disease management organization to manage the patient, as recited in independent claims 1 and 8. The

revenues and fees generated in independent claims 1 and 8 are dictated by the actual access of certain information stored on the database network site and not simply according the length of time a person is connected to the Internet.

For the foregoing reasons, applicant respectfully submits that the limitations of independent claims 1 and 8 and their respective dependent claims are not taught or suggested by the combination of cited prior art, and it is submitted that such claims are not obvious over *Brown* in view of *Lynam* or the other cited prior art. Reconsideration of these claims is respectfully requested.

The Combination of *Brown* and *Bahl* Fails to Teach or Suggest an Implantable Medical Device That Wirelessly Transmits Sensed Biologic Data to a Patient Accessible Electronic Interface

Independent claim 32 recites a computer implemented method involving an implanted medical device configured for automatic sensing of physiologic and biologic data of a patient and wirelessly transmitting that data, or portions thereof, to other components for storage on a database network site for allowing a user to remotely access such sensed physiologic and biologic data. In some embodiments, this allows for the real-time and continuous monitoring of physiologic and biologic data in a patient through use of an implantable medical device. This degree of interaction allows for more rapid and in-depth clinical analysis of disease symptoms and treatments. Such real-time access to physiologic and biologic patient data also facilitates administration of drug and other therapy in a more responsive and economic fashion.

The cited *Brown* reference fails to teach or suggest an implanted medical device that wirelessly transmits sensed physiologic and biologic patient data, such as to a patient accessible electronic interface for subsequent transmission to a database network site. Rather, the *Brown* monitoring system is directed to devices external to a patient's body that "transmit the measurements to the patient's remotely programmable apparatus through a standard connection cable 30." See col. 5, lines 1-3 of *Brown*. As can be seen, *Brown* discloses a physical connection cable in order to transmit data from a patient monitoring device, and as such *Brown* cannot be used for an implanted medical device that wirelessly transmits to other components for storage on a database network site for allowing a user to remotely access such sensed

physiologic and biologic data. Further, the cited *Lynam* and *Bahl* references are not directed to medical devices in manner whatsoever, and these cited prior art references further fail to teach or suggest an implanted medical device that wirelessly transmits sensed physiologic and biologic patient data.

Thus, it is respectively submitted that a *prima facie* case of obviousness cannot be maintained against independent claim 32 by the combination of *Brown* and *Lynam* (or *Bahl*), and reconsideration of this rejection is respectfully requested.

§ 103 Rejections Based on *Brown and Bahl*

Claims 33-34 and 39-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Brown* (US 5,997,476) in view of *Bahl* (US 6,834,341). Applicant respectfully traverses these rejections, and reconsideration is requested based on the following remarks.

Independent claim 33 was distinguished in the description above over the combination of *Brown* and *Bahl* in view of the failure of this combination of prior art to teach or suggest the real time monitoring of high relevance physiologic data through a database accessed through a website. It is thus respectfully submitted that independent claim 33 and its respective dependent claim 34 are allowable over the combination of *Brown* and *Bahl*.

The Combination of *Brown* and *Bahl* Fails to Teach or Suggest the Use of Implanted Medical Devices

Independent claims 39 and 40 recite a computer implemented patient management network and a system, respectively, that allow, among other features, high relevance physiologic data mined from implanted medical devices to be accessed through web site / server environment. Applicant notes that neither *Brown* nor *Bahl* teach or suggest that their inventions are capable of being used with implanted medical devices. *Bahl* is merely directed to a method of providing network access (e.g., access to the Internet) and *Bahl* is wholly unrelated to concept of collecting high relevance physiologic data from implanted medical devices. Further, *Brown* also fails to teach or suggest an implanted medical device capable of wirelessly transmitting

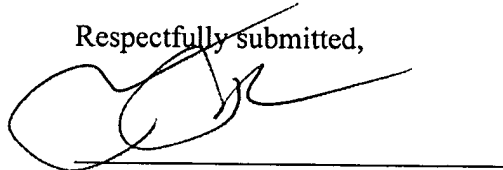
sensed physiologic and biologic patient data, such as to a patient accessible electronic interface for subsequent transmission to a database network site.

Rather, the *Brown* monitoring system is directed to devices external to a patient's body that "transmit the measurements to the patient's remotely programmable apparatus through a standard connection cable 30." See col. 5, lines 1-3 of *Brown*. From this, it can be seen that *Brown* requires a physical connection cable in order to transmit data from a patient monitoring device. As such, by requiring a standard connection cable 30, the monitoring devices 28 of *Brown* must be devices external to a patient's body and *Brown* cannot be used for an implanted medical device that wirelessly transmits to other components for storage on a database network site for allowing a user to remotely access such sensed physiologic and biologic data. *Brown* discloses examples of suitable external monitoring devices 28 including blood pressure cuffs, electronic weight scales, etc. (col. 5, lines 3-5). Thus, it respectfully submitted that the combination of *Brown* and *Bahl* fails to teach or suggest the use of an implanted medical device as recited in independent claims 39 and 40, and it is respectfully submitted that independent claims 39 and 40 are allowable over the combination of *Brown* and *Bahl*.

Conclusion

In each case, the pending rejections should be reconsidered in view of the amendments and remarks herein. Applicant believes that this case is in good condition for allowance, and a Notice of Allowance is earnestly solicited. If a telephone or further personal conference would be helpful, the Examiner is invited to call the undersigned, who will cooperate in any appropriate manner to advance prosecution. The Commissioner is directed and authorized to charge all additional required fees, except for the Issue Fee and the Publication Fee, to **Deposit Account Number 50-2638**. Please also credit any overpayments to said Deposit Account. Please ensure that Attorney Docket Number P0009618.00 is referred to when charging any payments or credits for this case.

Respectfully submitted,



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